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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,326	02/24/2004	Fredric J. Cohen	X-11057C	9685

25885 7590 07/25/2007

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EXAMINER
ANDERSON, JAMES D

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
07/25/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/785,326	COHEN ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 145-156* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 145-156* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 19 & 145-156 ARE PRESENTED FOR EXAMINATION

Applicants' Response and Information Disclosure Statements filed 6/15/2007 have been received and entered into the application. As reflected by the attached, completed copy of form 1449 the cited references have been considered.

Upon further consideration, the following rejections are newly applied. In view of the new rejections being applied against the pending claims, prosecution is reopened and the finality of the previous Office Action is *withdrawn*. Accordingly, this Office Action is **Non-Final**.

Petition to Revive Application No. 09/931,159

Receipt of the Petition to Revive application no. 09/931,159 is acknowledged. Said petition was granted on July 12, 2007. Accordingly, the 09/931,159 application was co-pending with the instant application at the time of filing. As such, the previous rejections under 35 U.S.C. 102(b) are hereby *withdrawn*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 145-156 are rejected under 35 U.S.C. § 102(b) as being anticipated by Black *et al.* (U.S. Patent No. 5,393,763; Issued Feb. 28, 1995) (newly cited art).

The instant claims recite a method of reducing the likelihood of incurring or developing estrogen-dependent breast cancer in a post-menopausal woman comprising administering raloxifene. Dependent claims recite the limitation wherein the woman is also diagnosed as having established osteoporosis.

Black *et al.* provides methods for inhibiting the loss of bone and are thus effective for the treatment of osteoporosis (Abstract). One of the most common types of osteoporosis is found in post-menopausal women (col. 1, lines 34-35). The methods of the invention comprise administering an effective amount of a compound of formula I as recited in column 2, lines 25-59. Such compounds include raloxifene as instantly claimed (cols. 7-8 and Examples). Doses of 0.1 to 1000 mg and more typically from about 200 to 600 mg are administered (col. 6, line 68 to col. 7, line 5). The instantly claimed dose is "about 60 mg". The "about" modifier expands the range of raloxifene that can be administered to a patient to reasonably include any effective amount, including those doses recited in Black *et al.* In the examples provided in the reference, raloxifene is administered to "post-menopausal women" (col. 19, lines 15-16 and claim 3), thus anticipating the instantly claimed patient population. Claim 2 of the '763 patent recites patients suffering from osteoporosis as instantly claimed in claims 153-156.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art

would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

In the instant case, it flows from the teachings of Black *et al.* that patients being treated with raloxifene so as to inhibit bone loss will naturally have a reduced likelihood of developing breast cancer. It is clear that Black *et al.* contemplate treating post-menopausal women with raloxifene and further contemplate treating patients having osteoporosis with raloxifene (*i.e.*, the same patient populations as instantly claimed). Because the same patient populations are being treated with the same drug, the instantly claimed result of such treatment would naturally occur in the patients being treated in the '763 patent.

Accordingly, the claims are deemed properly rejected as being anticipated by Black *et al.* Applicants' discovery of an additional, unappreciated result of treating post-menopausal women with raloxifene is not patentable over the '763 patent.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claim 19 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Black *et al.* (U.S. Patent No. 5,393,763; Issued Feb. 28, 1995) as applied to claims 145-156, *supra*.

Black *et al.* disclose as applied *supra*. The reference does not explicitly disclose the instantly claimed administration for at least six months. However, in the absence of a showing of unexpected results, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to administer raloxifene for as long was necessary to inhibit bone loss as disclosed in Black *et al.* As such, because the same patient population is being administered the same active agent, it flows from the disclosure of Black *et al.* that such extended treatment will lead to a reduced likelihood of incurring or developing estrogen-dependent breast cancer in post-menopausal women.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
Au 1614

July 19, 2007

Phyllis Spivack
PHYLLIS SPIVACK
PRIMARY EXAMINER
7/20/07